CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Advancing Stem Cell Research Under the Highest Ethical and Medical Standards

Scientific and Medical Accountability Standards Working Group

Teleconference July 27, 2007

July 18, 2008

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Items for Consideration

1. **Use of covered stem cell lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells***

2. **Limitations on payments for cells clarifying language**

3. **Requirements for use of somatic cells and human tissue**

1. Japanese Guidelines

- **SWG requested staff to review guidelines for inclusion in the MES regulations**
- **Japanese guidelines comparable to Canadian Institutes for Health Research (CIHR) guidelines**
- **Inclusion in the MES regulations would increase the number of cell lines available without additional SCRO review of procurement and derivation procedures**
- **Policy supports efforts to promote international exchange and collaboration**

2. Limitations on Payments

- **Existing regulations are duplicative with regard to language pertaining to the payments for commercially available cells**
- **Proposition 71 contained language addressing payments for cells**
- **Proposed revisions would only apply to third-party transactions**
- **Restrictions on payment to donors of gametes, embryos, somatic cells or human tissue not effected by revision**

3. Use of Somatic Cells & Human Tissue

- **Current language requires exact CIRM consent for use of somatic cells to derive a covered stem cell line**
- **Limits use of somatic cells collected before the effective date of the regulations**
- **Somatic cells collected before effective date are attractive for genetic reprogramming studies (e.g. use of somatic cell only, no oocytes) because they are scientifically well characterized**

Current Regulatory Language

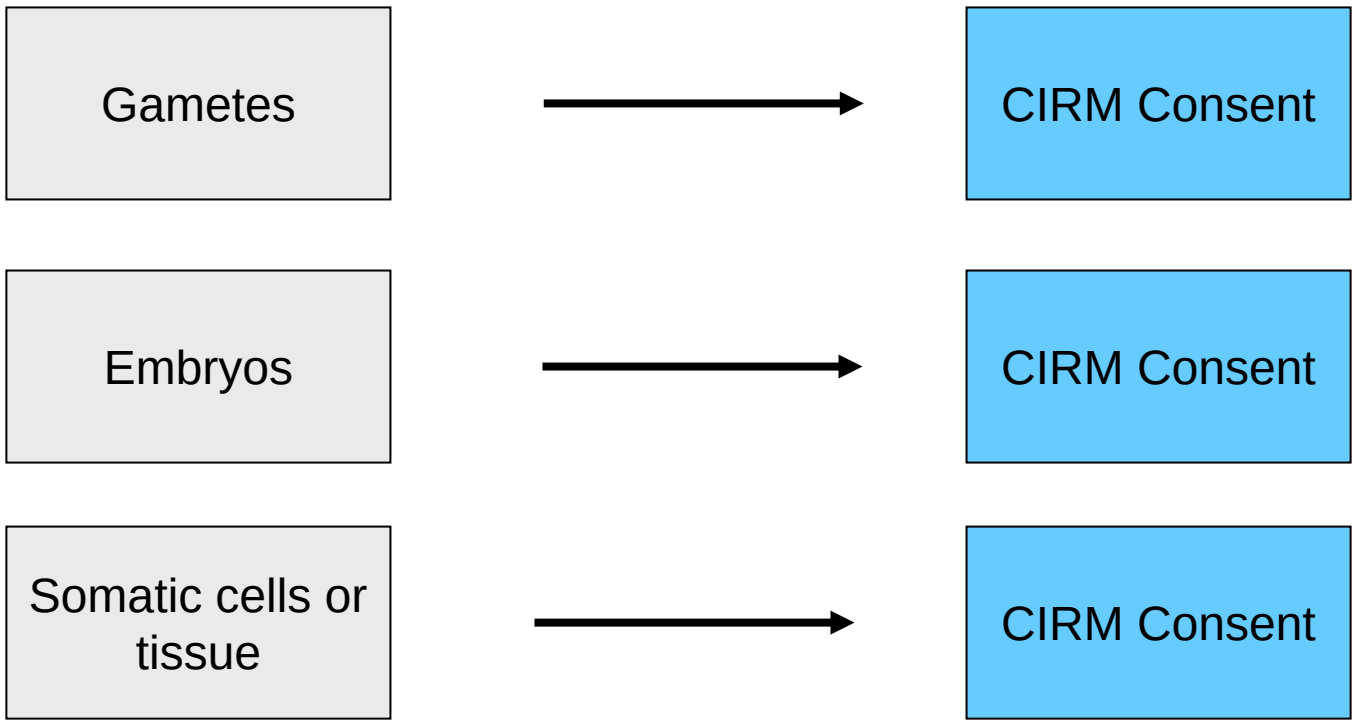
§ 100090. Additional Requirements for CIRM-Funded Derivation.

Where CIRM funds are to be used to derive new human stem cell lines, in addition to the requirements of Code of California Regulations, title 17, section 100080, subdivision (e), the SCRO committee must confirm that donors of gametes, embryos, somatic cells or human tissue have given voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100.*

* This section includes CIRM's exact consent requirements

Current Consent Requirement

If CIRM funds are to be used to derive new human stem cell lines from:



Current Consent Requirement

If CIRM funds are to be used to derive new human stem cell lines from:

Source Material for Derivation Research	Consent Requirement
Gametes	CIRM consent
Blastocysts / Embryo	CIRM consent
Somatic cells or tissue	CIRM consent

Flexible Option for Use of Somatic Cells

If CIRM funds are to be used to derive new human stem cell lines from:

Source Material for Derivation Research	Consent Requirement for CIRM-funded Derivation Research
Gametes	CIRM consent
Blastocysts / Embryo	CIRM consent
Somatic cells or tissue*	OHRP guidelines

* OHRP standard would apply to genetic “reprogramming” experiments. Experiments resulting in blastocysts formation / SCNT covered by CIRM consent consistent with NAS guidelines.

Flexible Option with Basic Research Limitation

If CIRM funds are to be used to derive new human stem cell lines from or used for human transplantation:

Source Material for Derivation Research	Consent Requirement for CIRM-funded Derivation Research	Requirement for Human Transplantation of Resulting Cell Lines
Gametes	CIRM consent	CIRM consent / Acceptably derived
Blastocysts / Embryo	CIRM consent	CIRM consent / Acceptably derived
Somatic cells or tissue*	OHRP guidelines	CIRM consent / Acceptably derived

* OHRP standard would apply to genetic "reprogramming" experiments. OHRP includes human subjects protections. Experiments resulting in blastocysts formation / SCNT or human transplantation covered by CIRM consent. Non-CIRM-derived cells for transplantation must be acceptably derived under existing regulations.

Question for SWG

If CIRM funds are to be used to derive new human stem cell lines from or used for human transplantation:

Source Material for Derivation Research	Consent Requirement for CIRM-funded Derivation Research	Requirement for Human Transplantation of Resulting Cell Lines
Gametes	CIRM consent	CIRM consent / Acceptably derived
Blastocysts / Embryo	CIRM consent	CIRM consent / Acceptably derived
Somatic cells or tissue*	?	?

Language Consistent with Flexible Option

§ 100090. Additional Requirements for CIRM-Funded Derivation (draft language for discussion).

Where CIRM funds are to be used to derive a covered stem cell line from human gametes, human embryos or human cells necessary for SCNT, the SCRO committee must determine that for all donors of these materials both the requirements of Code of California Regulations, title 17, section 100080, subdivision (e), and the requirements of Code of California Regulations, title 17, section 100100, subdivision (b), are met. These requirements do not apply to research intended to derive a covered stem cell line from human somatic cells provided the research does not require SCNT or the creation or use of a human embryo. The modification of an existing covered stem cell line shall not be considered a CIRM-funded derivation.

Language Consistent with Flexible Option

§ 100080. Acceptable Research Materials (draft language for discussion).*

(b) Covered stem cell lines used in CIRM-funded research derived from somatic cells that do not meet any of the requirements of subdivision (a) of this regulation are nevertheless "acceptably derived" provided: (1) the derivation did not require the transfer of a somatic cell nucleus into a human oocyte (SCNT) or the creation or use of a human embryo; and (2) the resulting cells have no codes or linkers of any sort maintained, either by the CIRM-funded researcher or a third party, that would permit access to identifiable private data or information about the living individual from whom the material was obtained.

* This language intended to enable the use of "outside" (non-CIRM) cell lines derived from somatic cell genetic reprogramming.